Exhibit 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION HILARY CONVERSE, Plaintiff, v. JOHNSON & JOHNSON, et al., Defendants.	MDL NO. 16-2738 (FLW) (LHG) Civil Action No.3:18-cv- 17586-FLW-LHG

EXPERT REPORT OF CHERYL C. SAENZ, M.D.

Case-specific opinions regarding Ms. Hilary Converse

Date: May 28, 2024

Cheryl C. Saenz, M.D.

Diagnosis and Treatment of Ovarian Cancer

Hilary Converse was born on October 28, 1948. In the summer of 2007, Ms. Converse presented to her general gynecologist of many years, Dr. Ellen Fine, with complaints of abdominal fullness and pelvic pressure, as well as urinary urgency. She was sent for a pelvic ultrasound and that study was performed on August 21, 2007. Findings included a right adnexa measuring 11.1*8.9*10.7cm with vascular flow to a dominant solid nodule within the mass measuring 3.7*3*3.4cm. Also noted with the complex mass were other smaller nodules. The interpretation of the radiologist was that these findings raise consideration for ovarian cancer, in particular the possibility of a papillary or clear cell carcinoma. Ms. Converse then sought consultation with a gynecologic oncologist and was seen at Memorial Sloan Kettering as well as Smilow Cancer Hospital at Yale-New Haven.

On September 5, 2007, Ms. Converse was taken to the OR by Dr. Peter Schwartz and underwent an exploratory laparotomy, total abdominal hysterectomy, bilateral salpingo-oophorectomy, omentectomy, peritoneal biopsies, para-aortic and pelvic lymph node dissections, collection of washings and repair of a left ureteral sharp injury. Operative findings included a large left pelvic mass, measuring 12 cm and filled with green fluid with intraoperative rupture. As the mass was reportedly mobile, it is unclear how the rupture occurred, unless it was actually adherent to some degree, as would be the case if it arose from endometriosis. No other lesions were found on the pelvic or abdominal peritoneum. Intraoperative frozen section was consistent with an adenocarcinoma, favoring high grade endometrioid cancer. Final pathology revealed a clear cell carcinoma of the left ovary, with the surface of the ovary being negative for carcinoma. The remainder of the tissues that were removed at the staging operation were negative for disease, and she was reported to have Stage IA disease. In deposition testimony, Dr. Schwartz was asked if there is anything in the "pathology report that would have told [him] as a clinician what was the cause of [Ms. Converse's] cancer?" He replied, "What this pathology report tells me is that it's likely this tumor arose in an endometriosis background and that's why they saw endometrioid initially on the frozen section, and we know that clear-cell and endometrioid are occurring in patients with endometriosis."[1] She was counseled that she would benefit from adjuvant chemotherapy and was referred to medical oncology.

Ms. Converse was counseled by Dr. Schwartz that given the clear cell histology of her ovarian cancer, she should be treated with taxane and platinum based chemotherapy. She received cycle #1 of paclitaxel and carboplatinum on September 21, 2007, and overall, she tolerated the chemotherapy well. She also enrolled in a clinical trial during the time that she was on chemotherapy which was evaluating the use of epoetin alpha in patients on chemotherapy. Cycle #6 of her treatment was provided to her on January 11, 2008. According to medical records, Ms. Converse has remained in remission from her ovarian cancer diagnosis since completing her chemotherapy approximately 16 years ago, and according to Gary Altwerger, MD in the division of gynecologic oncology at Smilow Cancer Hospital, was still without

[1] January 28, 2021 Deposition Transcript of Peter Schwartz, MD, p. 31, lines 19-25 & p. 32, lines 1-4.

evidence of disease on April 5, 2023.[2] Additionally, she had an appointment with her primary care provider, Stephanie Parillo, PA-C on January 8, 2024, in which ovarian cancer was not listed on her active problem list, and for her oncology issues, the notes state that she "checks in once a year."[3] Dr. Schwartz testified that although Ms. Converse's cancer could come back, he has "never seen, to [his] knowledge, a recurrence of ovarian cancer this late after a stage 1 ovarian cancer had been treated. So, to [his] knowledge, she really is as healthy as anybody can be following treatment for ovarian cancer."[4] Plaintiff's expert, Dr. Clarke-Pearson, similarly considers Ms. Converse to be cured of her ovarian cancer, stating "I think she's likely to be cured."[5]

Clinical Cancer Genetics

Shortly after Ms. Converse completed her chemotherapy for Stage IA ovarian cancer, she was seen in Cancer Genetic Counseling at Yale University School of Medicine by Danielle Campfield, MS and Allen E. Bale, MD. The indication for the referral was based upon her personal and cancer family history. On March 12, 2008, a letter was sent to Ms. Converse detailing the information that was gathered during these consults, as well as summarizing the discussions that were held.[6] Ms. Converse related the following family history in her initial genetics evaluation:

- She relates that she is of Ashkenazi Jewish descent, from both her maternal and paternal lineages.
- Patient diagnosed with Stage IA ovarian cancer at age 58.
- Mother, diagnosed with breast cancer at age 46 and non-melanoma skin cancer.
- Maternal uncle diagnosed with non-Hodgkin's lymphoma in his late 70s.
- Maternal grandmother diagnosed with pancreatic cancer at age 87.
- Father diagnosed with lung cancer in his 80s, tobacco user.
- Paternal aunt diagnosed with breast cancer in her 70s.
- Paternal cousin diagnosed with breast cancer in her 40s.

Ms. Converse was informed that several factors were found in her family that increase the probability that her cancer may be hereditary. These included her Ashkenazi heritage, early onset of cancer in her mother, and related cancers, such as breast and ovarian cancer found in the same family. Based on this family and personal cancer history, Ms. Converse was recommended to undergo genetic testing. On February 24, 2008, Ms. Converse's testing revealed that she did not harbor a mutation in either BRCA1 or 2. Importantly, the genetics counselors informed Ms. Converse that her results could be interpreted in several ways: "1) the cancers in [her] family are not hereditary (less likely based on [her] personal and family history)

[2] ConverseH-PPR-00275.
[3] ConverseH-PHPPB-00047-00048.
[4] January 28, 2021 Deposition Transcript of Peter Schwartz, MD, p. 67, line 25 & p. 68, lines 1- 4.
[5] August 26, 2021 Deposition Transcript of Daniel Clarke Pearson, MD, p. 358, line 10.
[6] CONVERSE_HILARY_SMILOWCANCERHOSPITAL_00045-00047.

or; 2) there is an undetectable mutation or a mutation in a different gene that is responsible for the cancers in [her] family."[7] The counselors went on to inform her that "we believe that you may be at an increased risk to develop breast cancer, even with your negative test results," and went on to discuss several risk reduction strategies for both Ms. Converse and her family members.[8] The counselors also encouraged her to contact them every 3-5 years for updated screening, risk reduction strategies and additional testing as more information becomes available.

In June 2014, Danielle Bonadies, MS, Assistant Director of Cancer Genetic Counseling sent another letter to Ms. Converse summarizing the information discussed to date. Ms. Converse was informed that "the pattern of cancers and ages of diagnosis in [her] family appears to be more than chance alone."[9] She was updated that although she had testing in 20 additional genes and no frank mutations were found, she was found to have two variants of uncertain significance in the ATM and TGFBR2 genes. Ms. Converse's mother (Rita Krevit) was also tested and found to have these same two variants, and the impact of these two variants remains unknown.[10] She was again counseled that even with the negative genetic testing results, she should be followed closely for breast cancer risk, and it was acknowledged that she was receiving increased surveillance by the Breast Center at Yale.[11] The genetics counselors also expressed concern for Ms. Converse's daughter, stating, "we recommend that your unaffected daughter consider herself at increased risk for breast and ovarian cancer." It was "strongly" recommended that Ms. Converse re-contact the genetic counselors prior to her daughter proceeding with planned risk reducing surgery as there may be additional testing that becomes available.

In May 2017, Ms. Converse was referred back to the genetics counselors to determine if any additional testing was recommended at that time and the medical records indicate that testing options for hereditary breast and ovarian cancer had not changed substantially since she had the testing that was performed in 2013-2014.[12] There are no records as to whether or not Ms. Converse has sought any additional consultation with the genetics counselors since the May 2017 documentation.

Past Medical History

- Hypertension
- Hypercholesterolemia
- Anxiety disorder
- GERD
- Cervical stenosis

[7] CONVERSE_HILARY_SMILOWCANCERHOSPITAL_00046.
[8] CONVERSE_HILARY_SMILOWCANCERHOSPITAL_00047.
[9] CONVERSE_HILARY_DRPETERSCHWARTZ_00003.
[10] CONVERSE_HILARY_DRPETERSCHWARTZ_00008.
[11] CONVERSE_HILARY_DRPETERSCHWARTZ_00004.
[12] ConverseH-YCGCMR-00043-00045.

- Cervicalgia/cervical myofascial pain
- Myalgia/myositis
- Interstitial cystitis
- Fibromyalgia
- Lymphedema
- Question of Lyme disease
- Irritable bowel syndrome
- Osteoarthritis
- Osteopenia
- Migraine headaches with aura
- Stage IA Clear Cell Carcinoma of the Ovary
- Tobacco use 25 years, last 1990

Past Surgical History

- Adenoidectomy
- Exploratory laparotomy, TAH/BSO, omentectomy, para-aortic and pelvic lymphadenectomy, peritoneal biopsies, left ureteral repair
- Cervical spine fusion
- Ventral hernia repair with mesh
- Foot fracture (right) with ORIF

Obstetrical/Gynecologic History

- Menarche at age 14
- Menopause in her mid-50s
- G2P2 with first child at age 25
- Breastfeeding – 13 months with son; few weeks with daughter
- Oral contraceptives – > 10 years
- Hormone replacement therapy – 10 years

Summary

I have performed a thorough review of Ms. Converse's medical records, the depositions of Hilary Converse, Marquis Converse, Jessica Hughes and Peter Schwartz, MD, as well as the Plaintiff Profile Forms, expert reports of Drs. Godleski and Clarke-Pearson, and the depositions of Dr. Clarke-Pearson. I have also reviewed the expert report of Dr. Juan Felix, defense expert in the field of gynecologic pathology.

Ms. Converse was diagnosed with Stage IA clear cell carcinoma of the left ovary in September 2007 (although based on the intraoperative rupture, it may be more appropriate to stage her cancer as IC). With appropriate surgery and an optimal debulking by Dr. Schwartz, followed by chemotherapy, Ms. Converse's cancer entered remission and she has remained disease-free for 16 years. Ms. Converse had negative germline testing of 20 genes; however, she also has two variants of uncertain significance, one in the ATM gene and one in the TGFB2 gene, both of

which are also mutated in her mother, who was diagnosed with breast cancer at 46 years old. The genetic counselors at Yale still assert that Ms. Converse is at an increased risk of breast cancer and her daughter is at an increased risk of breast and ovarian cancer, as there is still a possibility that Ms. Converse is carrying a germline mutation that has yet to be identified and that contributed to her development of ovarian cancer. This is supported by their recommendation that she and her daughter remain in intensive screening and check back in periodically with the genetics counseling office for new testing and screening information as the science evolves.

In addition to suspicion of an inherited risk factor for Ms. Converse's ovarian cancer, she has several other risk factors that placed her at an increased risk for the development of clear cell carcinoma of the ovary. These include her age, family history of breast cancer and Ashkenazi heritage, use of hormone replacement therapy, and the endometriosis that was found in the tissues that were removed at the time of her surgery. Ms. Converse was 58 years old at the time of her diagnosis of ovarian cancer. As the mean age of ovarian cancer diagnosis is 63 years old and the majority of women are diagnosed between ages 55-64, Ms. Converse, at age 58, was well within the age range of most women that are diagnosed with the disease.[13] Ms. Converse's mother was diagnosed with breast cancer at age 46 and it has been shown in large series that having a first-degree relative with breast cancer increases a woman's risk of developing ovarian cancer.[14,15] Being of Ashkenazi heritage also increased Ms. Converse's risk of developing ovarian cancer, regardless of her past genetic testing. Crawford et al. (2017) reported on women previously found to be negative for mutations in BRCA1/2.[16] These authors performed expanded panel testing on high-risk women previously found to be negative for mutations in BRCA 1/2 and reported that 9% of the women with ovarian cancer actually harbored inherited pathogenic mutations in genes with well-established ovarian cancer risk, including previously unidentified mutations in BRCA1/2.[17] Importantly, Ashkenazi Jewish women had elevated pathogenic mutation rates of 12% over other ethnicities, and as we know from Mrs. Converse's personal history, she is of Ashkenazi Jewish descent from both her paternal and maternal lineages.

The medical records document that Ms. Converse used hormone replacement therapy from 1997-2007, and she confirms the veracity of that documentation in deposition testimony.[18] Dr.

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[13] Ovarian Cancer Research Alliance *Risk Factors* (last accessed May 6, 2024) https://ocrahope.org/patients/about-ovarian-cancer/risk-factors/.

[14] Urban N., et al. (2015). Identifying post-menopausal women at elevated risk for epithelial ovarian cancer. *Gynecologic Oncology*. 139(2):253-60.

[15] Kazerouni N., et al. (2006). Family history of breast cancer as a risk factor for ovarian cancer in a prospective study. Cancer: *Interdisciplinary International Journal of the American Cancer Society.* 107(5):1075-83

[16] Crawford B., et al. (2017). Multi-gene panel testing for hereditary cancer predisposition in unsolved high-risk breast and ovarian cancer patients. *Breast Cancer Research and Treatment*. 163(2):383-90.

[17] Crawford B., et al. (2017). Multi-gene panel testing for hereditary cancer predisposition in unsolved high-risk breast and ovarian cancer patients. *Breast Cancer Research and Treatment*. 163(2):383-90.

[18] December 1, 2020 Deposition Transcript of Hilary Converse, p. 134, lines 4-7.

Clarke-Pearson incorrectly asserts in deposition testimony, that only women who use estrogen alone are at an increased risk, and women who use both estrogen and progesterone, do not increase their risk of developing ovarian cancer. He stated: "My understanding with regard to risk factors associated with hormone replacement therapy is that women that are taking estrogen and progesterone for their hormone replacement therapy are not at increased risk of ovarian cancer, whereas patients that are just taking estrogen alone are at increased risk"[19]

He goes on to say that he disagrees with the American Cancer Society on whether combination HRT is a risk factor for developing ovarian cancer.

> Q. So you disagree with the American Cancer Society because earlier you said you agreed with them?
>
> A: I disagree with regard to the group of women that take estrogen and progesterone for hormone replacement therapy.[20]

Multiple studies have shown that the use of HRT (both estrogen alone and estrogen in combination with progesterone), for five years or more increases a woman's risk of developing ovarian cancer, with increasing risk with increasing years of use, and both the OCRA and ACS identify the use of HRT as a well-established risk factor for the development of ovarian cancer on their respective websites.[21,22,23,24] With Ms. Converse's use of HRT for greater than 10 years, her risk of developing ovarian cancer was increased by 20-40%.

As stated above, Dr. Schwartz, Ms. Converse's gynecologic oncologist, believes that her cancer likely arose in a background of endometriosis. The epidemiologic literature has documented that the presence of endometriosis increases a woman's risk of developing ovarian cancer by two- to threefold.[25] That OR equates to an increase of 100-200% in the risk of developing ovarian cancer, and particularly seems to increase the risk of a woman developing the clear cell and endometrioid histologies.[26] Saavalainen and colleagues (2018) reported that women with ovarian endometriosis had an SIR of 10.1 (5.50,16.9) of developing ovarian clear cell carcinoma, and even when the endometriosis was not limited to the ovary, there was still a statistically

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[19] March 8, 2024 Deposition Transcript of Daniel Clarke Pearson, MD, p. 282, lines 13-19.
[20] March 8, 2024 Deposition Transcript of Daniel Clarke Pearson, MD, p. 282, line 20 – p. 283, line 2.
[21] Urban N., et al. (2015). Identifying post-menopausal women at elevated risk for epithelial ovarian cancer. *Gynecologic Oncology*. 139(2):253-60.
[22] Ovarian Cancer Research Alliance *Risk Factors* (last accessed May 6, 2024) https://ocrahope.org/patients/about-ovarian-cancer/risk-factors/.
[23] Collaborative Group on Epidemiological Studies of Ovarian Cancer. (2015). Menopausal hormone use and ovarian cancer risk: individual participant meta-analysis of 52 epidemiological studies. *The Lancet*. 385(9980):1835-42.
[24] American Cancer Society. Cancer Facts & Figures 2024. *American Cancer Society* 2024.
[25] Friedlander ML. (1998). Prognostic factors in ovarian cancer. *Seminars in Oncology*. 25(3):305-14.
[26] Friedlander ML. Prognostic factors in ovarian cancer. (1998). *Seminars in Oncology*. 25(3):305-14.

significant five-fold increase in the risk of clear cell histology.[27] Dr. Juan Felix performed a review of the tissues removed at the time of Ms. Converse's surgery on September 5, 2007, focusing in particular on the left ovary as this was the site of her clear cell carcinoma. Dr. Felix reports that "[a]reas of Ms. Converse's tumor had definitive evidence of non-neoplastic endometriotic tissue within cystic tumor. The lining in these areas reveal non-clear cell, occasionally ciliated epithelium with underlying endometriotic stroma and hemosiderin laden macrophages. These findings indicate that the cyst in which Ms. Converse developed clear cell carcinoma began as an endometrioma and that her cancer arose within and from it."[28] Based on the pathology findings of an endometrioma within her left ovary, Ms. Converse had the very type of endometriosis that was identified by Saavalainen et al. as increasing a woman's risk of developing clear cell carcinoma by over 900% more than the background population risk.[29] In deposition testimony, Dr. Clarke-Pearson incorrectly assumes that there was no evidence of endometriosis in Ms. Converse's pathology, as he assumes that Dr. Godleski looked for it when he performed his review.[30]

> Q: Did Dr. Godleski look to see if Ms. Converse's pathology showed evidence of endometriosis?
>
> A: I think he did. And so did the pathologist at Yale that looked at the original pathology, and there was no evidence of endometriosis.

In fact, the pathologist from Yale, Dr. Kowalski, makes no mention of endometriosis, neither its absence nor its presence, in the report from September 5, 2007. Instead, her microscopic report focuses solely on the absence or presence of malignancy in the tissues submitted from Ms. Converse's surgery.[31] There is also no indication at all in Dr. Godleski's report that he looked to see if there was endometriosis in Ms. Converse's left ovary as he only reports confirmation of the original histologic diagnosis. "The histologic slides …were reviewed with light microscopy, and the diagnosis of clear cell carcinoma of the ovary was confirmed."[32] The fact that Dr. Godleski did not perform a complete histologic review seems at best incomplete and at worst biased towards the conclusions he drew that talc caused Ms. Converse's ovarian cancer. Dr. Felix concurs, stating in his report, "[i]ndeed, Dr. Godleski either ignores or fails to appreciate the pathologic evidence in this case, which unequivocally demonstrates that Ms. Converse's clear cell carcinoma developed from pre-existing ovarian endometriotic cyst."[33] Although no distinct causal mechanism can be identified for Ms. Converse's clear cell ovarian cancer,

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[27] Saavalainen, L., et al. (2018). Risk of gynecologic cancer according to the type of endometriosis. *Obstetrics & Gynecology.* 131(6), 1095-1102.
[28] Expert Report of Juan Felix, MD, dated July 29, 2021, p.4.
[29] Saavalainen, L., et al. (2018). Risk of gynecologic cancer according to the type of endometriosis. *Obstetrics & Gynecology.* 131(6), 1095-1102.
[30] August 26, 2021 Deposition Transcript of Daniel Clarke Pearson, MD, p. 272, lines 16-22.
[31] CONVERSE_HILARY_YALENEWHAVENHOSPITAL_02086-02089
[32] Expert Report of John Godleski, MD, dated July 12, 2021, p. 2.
[33] Expert Report of Juan Felix, MD, dated July 29, 2021, p.11.

endometriosis was most likely a substantial contributing factor. Dr. Schwartz, Ms. Converse's background.[34]

Dr. Clarke-Pearson also cites to Dr. Godleski's report[35] in which Dr. Godleski claims that he found 4 particles that represent talc in Ms. Converse's tissues with 2 of the particles being found in the right pelvic lymph node, 1 of the particles being found in the anterior cervix and 1 particle being found in a right para-aortic lymph node.[36] Of note, none of these tissues contained cancer. Moreover, there is no evidence of an inflammatory response in the areas where Dr. Godleski states that he found talc particles.

While Ms. Converse states that she used baby powder daily from 1962-2017 for hygiene purposes, there is no credible scientific data to support the conclusion that the talc contributed to her development of ovarian cancer.

In his report and in testimony, Dr. Clarke-Pearson states that he has performed a differential diagnosis and concluded that Ms. Converse's clear cell ovarian cancer was caused by the perineal application of talc.

Dr. Clarke-Pearson has changed his testimony on two issues that are highly relevant to his specific causation opinion in this matter.

First, in February 2019, Dr. Clarke-Pearson concurred that we can never really know what causes ovarian cancer in any individual woman, stating:

A. What I think I understand your question being, if we can't identify a gene mutation, then we don't know what caused it. Is that what you're asking me?

Q. Yes.

A. Then the answer would be, yes, we don't know.[37]

Nonetheless, in deposition testimony in 2021, Dr. Clarke-Pearson stated that he can now determine the cause of an individual woman's ovarian cancer, retracting his prior testimony by stating, "Well, that was my answer at the time."[38] Yet even in that deposition, he almost immediately retreated to his prior opinion, agreeing that "there is no way to tell, in an individual woman who used talc, whether she got ovarian cancer because of her talc use" or would have developed it anyway. [39]

[34] January 28, 2021 Deposition Transcript of Peter Schwartz, MD, p. 31, lines 24-25.
[35] August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 271, lines 14-21.
[36] Expert Report of John Godleski, MD, dated July 12, 2021, p. 4.
[37] February 4, 2019 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 94, lines 4-11.
[38] August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 215, line 2.
[39] August 26, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 248 line 7- p. 249, line 2.

Second, in 2019, Dr. Clarke-Pearson was deposed in the MDL matter and was asked if talcum powder increases all subtypes of ovarian cancer. He replied:

A: I think the epidemiologic data would suggest that serous cancers are the most common but endometrioid are there. And the other study – other types of epithelial ovarian cancers – clear cell and mucinous – are so infrequent – they're rare cancers. And, therefore, we don't have statistical power to decide whether they're caused by talc or not.[40]

In 2021, however, after being retained by plaintiff's attorneys in the Converse matter, Dr. Clarke Pearson changed his mind, testifying:

A: I think many studies aren't powered. I think the Terry study with the pooled analysis is powered enough to associate the increased risk of talcum powder causing clear cell carcinoma of the ovary.

Q: And the Terry study, of course, was published in 2013, right?

A: I believe so.

Q: And it was on – it was a study that you considered prior to your deposition in February of 2019, correct?

A: Yes.

Q: And your deposition in February '19 was six years after that study was published, right?

A: Yes.

Q: And yet you testified in 2019 that the epidemiologic studies were not sufficiently powered, right?

A: Yes.

Q: So what changed?

A: I became a little bit clearer in terms of this – there is a large literature on the number of epidemiologic studies that are there to digest and understand.[41]

The only paper that Dr. Clarke-Pearson cites to support his contention that talc contributed to the risk of Ms. Converse developing clear cell ovarian cancer is the paper published by Terry et

[40] February 4, 2019 Deposition Transcript of Daniel L. Clarke-Pearson, MD, p. 195, lines 16-23.
[41] August 26, 2021 Deposition Transcript of Daniel L. Clarke-Pearson, MD, p. 302, lines 11-25 & p. 303, lines 1-11.

al. in 2013.[42] If one actually performs a thorough analysis of the 9 epidemiologic studies that have published an analysis on the clear cell histologic subtype and the genital application of talc, there is only one study that demonstrates a statistically significant association and that is the Terry 2013 pooled analysis.[43,44,45,46,47,48,49,50,51]

Author	Clear Cell O.R. (C.I.)
Wong	1.6 (0.6-4.3)
Mills	0.63 (0.15-2.64)
Merritt	1.08 (0.68-1.72)
Terry	1.24 (1.01-1.52)
Cramer	1.01 (0.65-1.57)
Berge	0.98 (0.72-1.23)
Penninkilampi	1.02 (0.75-1.39)
Taher	0.63 (0.15-2.65)
O'Brien	1.17 (0.73-1.89)

There are problems with the Terry study, however, in that the numbers *simply don't add up*. Terry states that she pooled datasets from 8 different studies, some of which were previously published and some of which were not, and importantly included cases from the New England Consortium (NEC) which provided *276* cases of clear cell carcinoma leading to an OR of 1.24 (1.01,1.52). It is notable that 3 years later in 2016, Cramer et al., published using the same NEC dataset and reported having only *114* cases of clear cell carcinoma and found no increased risk

[42] Terry KL., et al. (2013). Genital powder use and risk of ovarian cancer: A pooled analysis of 8,525 cases and 9,859 controls. *Cancer Prevention Research*. 6(8):811-21.
[43] Wong C., et al. (1999). Perineal talc exposure and subsequent epithelial ovarian cancer: A case-control study. *Obstetrics & Gynecology*. 93:372-6.
[44] Mills PK., et al. (2004). Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *International Journal of Cancer*. 112:458-64.
[45] Merritt MA., et al. (2008). Talcum powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer. *International Journal of Cancer*. 122(1):170-6.
[46] Terry KL., et al. (2013). Genital powder use and risk of ovarian cancer: A pooled analysis of 8,525 cases and 9,859 controls. *Cancer Prevention Research*. 6(8):811-21.
[47] Cramer DW., et al. (2016). The association between talc use and ovarian cancer: A retrospective case-control study in two US states. *Epidemiology*. 27(3):334-46.
[48] Berge W., et al. (2018). Genital use of talc and risk of ovarian cancer: a meta-analysis. *European Journal of Cancer Prevention*.27(3):248-57.
[49] Penninkilampi R., et al. (2018). Perineal talc use and ovarian cancer: A systematic review and meta-Analysis. *Epidemiology*. 29(1):41-9.
[50]Taher M., et al., (2019). Critical Review of the Association between Perineal Use of Talc Powder and Risk of Ovarian Cancer. *Reproductive Toxicology*. 90:88-101.
[51] O'Brien, KM, et al. (2020). Association of powder use in the genital area with risk of ovarian cancer. *JAMA*. 323(1), 49-59.

in the subtype analysis for clear cell carcinoma OR 1.01 (0.65,1.57).[52] It is unclear why the Terry analysis includes an additional 162 clear cell cases. The fact that the Cramer paper finds no association from the same dataset further undermines Dr. Clarke-Pearson's opinions.

Dr. Clarke-Pearson also misapplied the epidemiological concept of an odds ratio to reach a conclusion on specific causation. In 2024, Dr. Clarke-Pearson initially confirmed his prior testimony from 2021 testified that "talc contributed 30% to Ms. Converse's clear cell cancer" based on "increased risk" shown in epidemiological studies.[53] Then, midway through his 2024 deposition, he changed his opinion and testified that 42% of Ms. Converse's clear cell cancer was caused by talc use (based on a tale in the Penninkilampi meta-analsis). This is a misapplication of epidemiological principles. A relative risk, even if it is affected by bias or other limitations, is not directly translatable to an individual's attributable risk of a cancer diagnosis. And certainly, the data on which Dr. Clarke-Pearson relies do not allow for such a conclusion.

"Penninkilampi's table" refers to Table 2 of the Peninkilampi and Eslick (2018) meta-analysis. That table, which pooled the results of a 24 case-control studies, reported an odds ratio of 1.42 (95%CI: 1.25-1.61) for all epithelial ovarian cancer cases among women with more than 3600 lifetime talc applications.[54] The same table, in a section Dr. Clarke-Pearson ignores, shows that there is no effect for clear-cell cancer, however (OR: 1.02, 95%CI 0.75-1.39).[55] As discussed in my general causation report, each histological subtype has a different molecular profile and can be associated with different risk factors. Understanding that epithelial ovarian cancer is not just one entity and is a composite of at least five different diseases, each with its own set of risk factors and molecular mutations is integral to understanding the pathogenesis of these diseases. To ignore these facts, as does Dr. Clarke-Pearson –

> Q. As of 2024, do you believe that high-grade serous ovarian cancer, clear cell carcinoma, and endometrioid ovarian cancer all have the same pathogenesis?
>
> A. I don't have an opinion about that.[56]

does nothing but hold back the science and our ability to actually potentially cure patients afflicted with this disease.

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[52] Cramer DW., et al. (2016). The association between talc use and ovarian cancer: A retrospective case-control study in two US states. *Epidemiology*. 27(3):334-46.
53 August 27, 2021 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 462:9-24.
54 Penninkilampi R., et al. (2018). Perineal talc use and ovarian cancer: A systematic review and meta-Analysis. *Epidemiology*. 29(1):41-9.
[55] Penninkilampi R., et al. (2018). Perineal talc use and ovarian cancer: A systematic review and meta-Analysis. *Epidemiology*. 29(1):41-9.
[56] March 8, 2024 Deposition Transcript of Daniel Clarke-Pearson, MD, p. 277:3-7.

Conclusion

There is no credible scientific data to support the conclusion that talc contributed to Ms. Converse's development of ovarian cancer. The peer-reviewed scientific literature, nationally recognized and respected healthcare organizations (NCI, CDC, ACS, FDA), and the professional societies (SGO, ACOG) to which I belong, all maintain the position that talc use does not cause ovarian cancer. Ms. Converse had many other well-established risk factors that increased her risk of developing the disease (age, Ashkenazi heritage, endometriosis, use of HRT). All of the opinions herein are to a reasonable degree of medical probability. In addition, all of the general causation opinions contained in my General Expert Report dated May 21, 2024 are also incorporated herein.

MATERIALS RELIED ON AND CONSIDERED BY DR. CHERYL SAENZ

PLAINTIFF PROFILE FORMS

1. Plaintiff Profile Form of Hilary Converse
2. 06/30/2020 First Amended Plaintiff Profile Form of Hilary Converse
3. 11/25/2020 Second Amended Plaintiff Profile Form of Hilary Converse

EXPERT REPORTS

1. 07/02/2021 Amended Expert Report of Daniel Clarke-Pearson, MD
2. 07/12/2021 Expert Report of John Godleski, MD
3. 07/15/2021 Amended Expert Report of Daniel Clarke-Pearson, MD
4. 07/29/2021 Expert Report of Juan Felix, MD
5. 11/15/2023 Amended Rule 26 Expert Report of Daniel-Clarke Pearson, MD

DEPOSITION TRANSCRIPTS

1. 02/04/2019 Deposition Transcript of Daniel Clarke-Pearson, MD
2. 12/01/2020 Deposition Transcript of Hilary Converse
3. 01/28/2021 Deposition Transcript of Peter Schwartz, MD
4. 05/12/2021 Deposition Transcript of Marquis Converse
5. 05/12/2021 Deposition Transcript of Jessica Hughes
6. 08/26/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 1)
7. 08/27/2021 Deposition Transcript of Daniel Clarke-Pearson, MD (Vol. 2)
8. 01/17/2024 Deposition Transcript of Daniel Clarke-Pearson, MD
9. 03/08/2024 Deposition Transcript of Daniel Clarke-Pearson, MD

MEDICAL RECORDS

1. Advanced Diagnostic Pain (ConverseH-ADPTCMR-00001-00022)
2. Costco Pharmacy (ConverseH-CPCO-00001-00003; CONVERSE_HILARY_COSTCOPHARMACY_00001)
3. CT Neuroscience (ConverseH-CNPCMR-00001-00031)
4. CT Orthopaedic Specialists (ConverseH-COSPCMR-00001-00129)
5. Comprehensive Gynecology of CT (ConverseH-CGCTMR-00001-00023, ConverseH-CGCTMR-00035-00042, ConverseH-CGCTMR-00045, ConverseH-CGCTMR-00056-00062, ConverseH-CGCTMR-00066-00069, ConverseH-CGCTMR-00071, ConverseH-CGCTMR-00080-00082, ConverseH-CGCTPB-00001-00009)
6. Connecticut Vascular Center (ConverseH-CVCMR-00001-00006)
7. Costco Pharmacy (ConverseH-CPCO-00008-00016)
8. CVS Pharmacy (ConverseH-CVSCICO-00001-00005)
9. Digestive Disease Center of CT (ConverseH-DDCCTMR-00001-00035)

10. Fine, Emily MD (ConverseH-FineE-00001-00196, CONVERSE_HILARY_DREMILYFINE_00072, CONVERSE_HILARY_DR_EMILY_FINE_BILLING_00001-00026)
11. Giant Foods Pharmacy (ConverseH-GFPCO-00001-00015)
12. Greater Waterbury Imaging (ConverseH-GWICMR-00001-00003)
13. Griffin Health Services (ConverseH-GHSCMR-00001-00033)
14. Hammers Healthcare Imaging (ConverseH-HHIMR-00001-00010)
15. Interventional Spine and Sports Medicine (ConverseH-ISSMPCMR-00252-00268)
16. Nadelmann, Jared MD (ConverseH-CVCMR-00001-00006)
17. Kitaj Headache Center (ConverseH-KHCMR-00001-00144)
18. Ko, Christine, MD (ConverseH-KoC-00001-00004)
19. Lui, Felix Yuehon, MD (ConverseH-YuehonLFMD-00001-00034; ConverseH-LuiDFYMD-00001-00023)
20. Mediquick Cheshire (ConverseH-MCMR-00013-00029)
21. Memorial Sloan-Kettering Cancer Center (ConverseH-MSKCCMR-00001-00040)
22. Myriad Genetics (ConverseH-MGLIMR-00001-00062)
23. Nadelmann, Jeremy (ConverseH-NadelmannJ-00001-00091)
24. Naugatuck Valley Radiology (ConverseH-NVRAINPB-00001-00002; ConverseH-NVRMR-00001-00022)
25. Neurosurgery, Orthopaedics & Spine Specialists (ConverseH-NOSSPCMR-00001-00011)
26. Opticare Eye Health (ConverseH-OEHVCMR-00001-00010)
27. Optum Rx (ConverseH-OR-00001-00229. ConverseH-OR-00230-00235, ConverseH-OR-00237-00242, ConverseH-OR-00244-00337)
28. Plaintiff Produced Medical Records:
    CONVERSE_HILARY_COSTCOPHARMACY_00001
    CONVERSE_HILARY_CVSCAREMARK_000001-000004
    CONVERSE_HILARY_DIGESTIVE_CNTR_000001-000034
    CONVERSE_HILARY_DR_NADELMANN_000001-000006
    CONVERSE_HILARY_DR_ROBERTS_000001-000018
    CONVERSE_HILARY_DR_SCHWARTZ_000125-00278
    CONVERSE_HILARY_DREMILYFINE_00001-00071
    CONVERSE_HILARY_DRPETERSCHWARTZ_00001-00130
    CONVERSE_HILARY_FELIX_YUEHON_LUI_000001-000008
    CONVERSE_HILARY_GENETICSTESTING_000001-000025
    CONVERSE_HILARY_GRIFFINHOSPITAL_000001-000014
    CONVERSE_HILARY_MEM_SLOAN_KETTERING_000001-000021
    CONVERSE_HILARY_NAUGATUCKRADIOLOGY_000001-000008
    CONVERSE_HILARY_NEWHAVEN_GYN_MEDS_000001-000086
    CONVERSE_HILARY_NOS_SPECIALISTS_000001-000010
    CONVERSE_HILARY_NUERO_ORTHO_SPINE_000001-000010

CONVERSE_HILARY_PROHEALTHPHYSICIANSOFHAMDEN_00001-00834
ConverseH-PPR-00001-00277
CONVERSE_HILARY_QUEST_NORECS_000001-000002
CONVERSE_HILARY_S_NEWENGLAND_ENT_000001-000028
CONVERSE_HILARY_SMILOW_CANCER_HOSPITAL_000951-001839
CONVERSE_HILARY_SMILOWCANCERHOSPITAL_00001-00950
CONVERSE_HILARY_WATERBURYHOSP_RECSPURGED_00001
CONVERSE_HILARY_WATERBURYIMAGING_000001-000002
CONVERSE_HILARY_WATERBURYORTHO_000001-000002
CONVERSE_HILARY_WHITNEYIMAGING_000001-000013
CONVERSE_HILARY_WOMANSHEALTHCT_000001-000002
CONVERSE_HILARY_YALE_NEWHAVENHEALTH_000001-000463
CONVERSE_HILARY_YALENEWHAVENHOSPITAL_00001-02089
ConverseH-ADPTCMR-00001-00022
ConverseH-CNPCMR-00001-31
ConverseH-CPCO-00001-00005
ConverseH-CVSCICO-00001-00005
ConverseH-DDCCTMR-00001-00035
ConverseH-FineE-00001-00201
ConverseH-GFPCO-00001-00008
ConverseH-GHSMR-00001-00033
ConverseH-GWICMR-00001-00003
ConverseH-HHIMR-00001
ConverseH-HHIMR-00003-00010
ConverseH-ISSMPCMR-00001-0251
ConverseH-KHCLLCPB-00014-00034
ConverseH-KHCMR-00001-00139
ConverseH-KOC-00001-00004
ConverseH-LuiF-00001-00023
ConverseH-MCMR-00001-00007
ConverseH-MGLIMR-00001-00062
ConverseH-MSKCCMR-00001-00040
ConverseH-MSMR-00001-00111
ConverseH-NadelmannJ-00001-00091
ConverseH-NOSSPCMR-00001-00011
ConverseH-NVRMR-00001-00022
ConverseH-OR-00001-00146
ConverseH-PHPMRI-00001-00534
ConverseH-QDNICVA-00001-00004
ConverseH-QDW-00001-00060
ConverseH-ROBERTSK-00001-00025

ConverseH-RSMMD-00001-00088
ConverseH-SGMCRad-00001-00003
ConverseH-SMHMR-00001-00073
ConverseH-SNEENTFPSGLLPMR-00001-00032
ConverseH-WALGREENS-00001-00034
ConverseH-WHRad-00001-00004
ConverseH-WICMR-00001-00013
ConverseH-WNMR-00001-00020
ConverseH-WOAPCMR-00001-00013
ConverseH-YALENEWHAVENHOSP-00001-02089
ConverseH-YBCMR-00001-00065
ConverseH-YCCMR-00001-01642
ConverseH-YCCPATH-00001
ConverseH-YCGCMR-000001-00027
ConverseH-YMDMR-00001-00118
ConverseH-YMSOSCHMR-00001-00162
ConverseH-YNHGOAMR-00001-00219
ConverseH-YNHHCMR-00001-00122
ConverseH-YNHHLMR-00001-00244
ConverseH-YNHHMR-00001-00316
ConverseH-YSIMR-00006-00079
ConverseH-YUEHONLUIF-00001-00034
Converse-YUGOCMR-00001-00181
ConversH-USPCMR-00001-00049
HCONVERSE-PL-00001-00834
ConverseH-PHPPB-00042-00054

29. Pro Health Physicians (ConverseH-PHPMR-00001-00732)
30. Quest Diagnostic-Nichols Institute (ConverseH-QDNICVA-00001-00004)
31. Quest Diagnostic-Wallingford (ConverseH-QDW-00001-00060)
32. Roberts, Kurt, MD (ConverseH-RobertsDK-00001-00025)
33. Schwartz, Peter, MD (ConverseH-SchwartzP-00001-00065; CONVERSE_HILARY_DRPETERSCHWARTZ_00001-00130)
34. Southern New England ENT & Facial Plastic Surgery Group (ConverseH-SNEENTFPSGLLPMR-00001-00032)
35. Spring Glen Medical Center (ConverseH-SGMCRad-00001-00003)
36. St. Mary's Hospital (ConverseH-SMHMR-00001-73; ConverseH-SMHPath-00001-00007; ConverseH-SMHRad-00001-00009)
37. Urology Specialists (ConverseH-USPCMR-00001-00053)
38. Walgreens (ConverseH-Walgreens-00001-00057)
39. Walmart (ConverseH-WMCO-00001-00009)
40. Waterbury Neurology (ConverseH-WNMR-00005-00020)

41. Whitney Imaging Center (ConverseH-WICMR-00001-00003)
42. Yale Bone Center (ConverseH-YBCMR-00001-00019)
43. Yale Cancer Center (ConverseH-YCCMR-00001-01642; ConverseH-YaleCancerCtrPath-00001; ConverseH-YCCPath-00002-00004)
44. Yale Cancer Genetics Counseling (ConverseH-YCGCMR-00001-00065)
45. Yale Medical Dermatology (ConverseH-YMDMR-00001-00141)
46. Yale Medical Group (ConverseH-YMGMR-00001-00147)
47. Yale Medical Oncology (ConverseH-YMOMR-00001-00492)
48. Yale Medicine Surgical Oncology at Smilow Cancer Center (ConverseH-YMSOSCHMR-00163-00174, ConverseH-YMSOSCHMR-00176-00180, ConverseH-YMSOSCHMR-00182-00193, ConverseH-YMSOSCHMR-00195-00200, ConverseH-YMSOSCHMR-00207-00211, ConverseH-YMSOSCHMR-00214-00231, ConverseH-YMSOSCHMR-00233-00235, ConverseH-YMSOSCHPB-00047-00056)
49. Yale New Haven Breast Center (ConverseH-YNHBCMR-00001-00150)
50. Yale New Haven Gynecologic Oncology (ConverseH-YNHGOAMR-00001-00219)
51. Yale New Haven Hospital (ConverseH-YNHHMR-00001-00316; ConverseH-YNHHPath-00001-00020)
52. Yale New Haven Hospital Cytology (ConverseH-YNHHCMR-00001-00122)
53. Yale Spine Institute (ConverseH-YSIMR-00006-00086)
54. Yale University Gynecologic Oncology Center (ConverseH-YUGOCMR-00182-00524)
55. Yale University School of Med (ConverseH-YUSOMPATH-00001-00003)
56. YM Surgical Oncology (ConverseH-YMSOSCHMR-00001-00162)

LITERATURE

1. American Cancer Society. Cancer Facts & Figures 2024. *American Cancer Society* 2024.
2. Berge W., et al. (2018). Genital use of talc and risk of ovarian cancer: a meta-analysis. *European Journal of Cancer Prevention*. 27(3):248-57.
3. Collaborative Group on Epidemiological Studies of Ovarian Cancer. (2015). Menopausal hormone use and ovarian cancer risk: individual participant meta-analysis of 52 epidemiological studies. *The Lancet*. 385(9980):1835-42.
4. Cramer DW., et al. (2016). The association between talc use and ovarian cancer: A retrospective case-control study in two US states. *Epidemiology*. 27(3):334-46.
5. Crawford B., et al. (2017). Multi-gene panel testing for hereditary cancer predisposition in unsolved high-risk breast and ovarian cancer patients. *Breast Cancer Research and Treatment*. 163(2):383-90.
6. Friedlander ML. Prognostic factors in ovarian cancer. (1998). *Seminars in Oncology*. 25(3):305-14.
7. Kazerouni N., et al. (2006). Family history of breast cancer as a risk factor for ovarian cancer in a prospective study. Cancer: *Interdisciplinary International Journal of the American Cancer Society.* 107(5):1075-83

8. Merritt MA., et al. (2008). Talcum powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer. *International Journal of Cancer*. 122(1):170-6.
9. Mills PK., et al. (2004). Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *International Journal of Cancer*. 112:458-64.
10. O'Brien, KM, et al. (2020). Association of powder use in the genital area with risk of ovarian cancer. *JAMA*. 2020; 323(1), 49-59.
11. Ovarian Cancer Research Alliance *Risk Factors* (last accessed May 6, 2024) https://ocrahope.org/patients/about-ovarian-cancer/risk-factors/.
12. Penninkilampi R., et al. (2018). Perineal talc use and ovarian cancer: A systematic review and meta-Analysis. *Epidemiology*. 29(1):41-9.
13. Saavalainen, L., et al. (2018). Risk of gynecologic cancer according to the type of endometriosis. *Obstetrics & Gynecology*. 2018; 131(6), 1095-1102.
14. Taher M., et al. (2019). Critical Review of the Association between Perineal Use of Talc Powder and Risk of Ovarian Cancer. *Reproductive Toxicology*. 90:88-101.
15. Terry KL., et al. (2013). Genital powder use and risk of ovarian cancer: A pooled analysis of 8,525 cases and 9,859 controls. *Cancer Prevention Research*. 6(8):811-21.
16. Urban N., et al. (2015). Identifying post-menopausal women at elevated risk for epithelial ovarian cancer. *Gynecologic Oncology*. 139(2):253-60.
17. Wong C., et al. (1999). Perineal talc exposure and subsequent epithelial ovarian cancer: A case-control study. *Obstetrics & Gynecology*. 93:372-6.

ADDITIONAL MATERIALS

1. Saed Confidential Documents (SAED_SEPT222021_SUPPL_000001-399